REMARKS

By the amendments, Applicants do not acquiesce to the propriety of any of the previous rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

Claim Amendments

Claims 1-14 have been canceled.

New claims 15-28 find support in the canceled claims as follows:

New claim	Previously pending, now canceled claim
15	1
16	2
17	3
18	4
19	5
20	6
21	7
22	8
23	9
24	10
25	11
26	12
27	13
28	14

Support for the limitation “suitable for coating on an implanted biomedical device” in claims 15 and 26 can be found in the specification in paragraph 0028, lines 1-3.

Support for the limitation “biocompatible” when referring to the coating in claims 15-28 can be found in the specification in paragraph 0020.

No new matter has been introduced as a result of the claim amendments.

35 U.S.C. §112 Rejections

The Office has rejected claim 7 under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Previously pending, now canceled, claim

7 corresponds to new claim 21. Specifically, the Office objects to the use of kiloDaltons (kDa) to define molecular weights for the polymers. The Office states that the Applicant should report polymer molecular weights as number average molecular weight (M_n) or weight average molecular weight (M_w). The Applicants respectfully direct the Office to Table 2 wherein M_w is defined as "weight average." The use of kDa in new claim 21 is supported by the M_w data of Table 5 of the present application which is reported in kDa. In addition, kiloDaltons are a unit of measure known in the art for classifying weight average and number average molecular weights.[1] Since kDa is a unit of measure known to, and used by, skilled artisans, it is not improper to use it in the claims. Accordingly, the Applicants request reconsideration and withdrawal of this rejection.

35 U.S.C. § 103(a) Rejections

The Office has rejected claims 1-14 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 6,835,759 ("Bradford"). Previously pending, now canceled, claims 1-14 correspond to new claims 15-28, respectively. The Applicants respectfully disagree; however, in order to expedite prosecution, new claims 15 and 26 recite wherein the formulation is suitable for coating on an implantable biomedical device and further recite that the coatings are biocompatible. Bradford does not render obvious a polymer formulation suitable for application onto an implantable biomedical device, nor does it motivate one skilled in the art to the do the same. Bradford teaches a polymer which would direct a skilled artisan to utilize "one or more fillers or pigments" [column 13, line 9] in the polymer formulations. Further, Bradford teaches a skilled artisan that a suitable filler includes "talc" [column 14, line 52].

When selecting biocompatible coatings for implantable medical devices, one skilled in the art must be cautious as to the selection of the components of the polymer formulation. Talc, for example, is known to cause pulmonary micro emboli and even

[1] Armstrong, et al., Improved molecular weight analysis of streptococcal hyaluronic acid by size exclusion chromatography. Biotechnology Techniques 1995: 9 (7) Pp. 491-496. (See Abstract). Submitted with the response filed December 27, 2007.

death if administered intravenously.[2] Talc has also been shown to be a toxic carcinogenic species and is present in a high percentage of dissected ovarian tumors.[3] A skilled artisan would not prepare a biocompatible coating suitable for an implantable biomedical device from such an ingredient.

In addition, the teachings of Bradford direct the skilled artisan toward using pigments to enhance the color and visual effect of the polymer [column 13, lines 51-67 and column 14, lines 1-22]. One skilled in the art of coating implantable biomedical devices is not concerned with the visual appeal since the coating will not be seen after the device is implanted. Therefore, the use of "metal flake pigments" [column 13, lines 51-67], "inorganic color pigments" [column 14, lines 1-13], and "organic color pigments" [column 14, lines 14-22] may not be appropriate for an implantable biomedical device and would require extensive testing by a skilled artisan to determine their safety. More importantly, a skilled artisan attempting to prepare a biocompatible coating suitable for an implantable biomedical device would not seek the teachings of a reference concerned with the visual appearance of a polymer.

In sum, Bradford does not teach a biocompatible coating suitable for use with an implantable biomedical device according to the present claims. Rather, Bradford teaches the use of fillers and pigments for use in the polymer formulation. Therefore a skilled artisan attempting to prepare an invention according to the present claims would not have sought Bradford's teachings. Accordingly, the Applicants request reconsideration and withdrawal of this rejection.

Additionally, the Office has rejected claims 1-14 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 6,162,511 ("Garnett"). As discussed above, originally filed, now canceled, claims 1-14 correspond to new claims 15-28, respectively and new claims 15 and 26 include the limitation wherein the formulation is suitable for coating on an implantable biomedical device and further recite that the coatings are

[2] Hollinger M.A., Pulmonary toxicity of inhaled and intravenous talc. Toxicology Letters 1990: 52 (2) Pp. 121-127. (Abstract). Submitted with the response filed December 27, 2007.

[3] Cook, et al., Perneal Powder Exposure and the Risk of Ovarian Cancer. American Journal of Epidemeology 1997: 145 (5) Pp. 459-465. Submitted with the response filed December 27, 2007.

biocompatible, neither of which are taught or suggested by Garnett. Garnett does not disclose a biocompatible coating applicable for implantable medical devices, but rather coatings "with high pigment or filler loadings" [column 2, line 12-13]. As discussed above, the use of pigments may not be appropriate for an implantable biomedical device and would require extensive testing by a skilled artisan to determine their safety. Further, Garnett teaches the use of talc [column 4, line 1], which as discussed above may be harmful to humans.

In addition, Garnett preferably includes one or more flame retardant additives to the composition [column 5, lines 26-27], which are not suitable for an implantable biomedical device. In fact, the use of flame retardants in biocompatible coatings for implantable biomedical devices would require extensive testing in order to determine their safety.

In sum, Garnett teaches a polymer formulation for coating a substrate which does not include biocompatible coatings suitable for coating an implantable biomedical device. Rather, Garnett teaches the use of fillers, pigments, and flame retardants for use in the polymer formulation. In other words, a skilled artisan attempting to prepare a biocompatible coating for an implantable biomedical device according to the present claims would not have sought Garnett's teachings. Accordingly, Applicants request reconsideration and withdrawal of this rejection.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484

Respectfully submitted,

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